The court of appeals may well have been correct when it observed that the rationales underlying treating commercial success as an indicium of nonobviousness tie it "directly to the practical, financial source of impetus for research and development." (App. 23a.) However, it is incorrect that "that chain of inferences fails on the[] facts" of this case. (*Id.*) Merck had an incentive to attempt to move to weekly dosing of Fosamax: had one of its competitors introduced a weekly-dosing form of another bisphosphonate, it would have lost considerable ground in the osteoporosis treatment market.

Unfortunately, the rule announced by the court of appeals, rooted in its erroneous conception of the appropriate market, will itself "fail on the facts" of nearly every case involving improvement patents. As this Court has noted, "most inventions represent improvements on some existing article, process, or machine." *General Electric Co.*, 304 U.S. at 368. And in the vast majority of cases involving improvement patents, they will represent but one means of meeting an existing market need. For this reason, a rule, under which "commercial success for an improvement is irrelevant when a prior patent dominates the basic invention" (App. 39a (Lourie, J., dissenting)), would have wide-reaching deleterious effects. Holders of existing patents will confront unique and unjustifiable burdens in defending improvement patents as part of their efforts to remain competitive. And this, in turn, will diminish their incentive to continue innovating.

In short, the rule announced by the court of appeals undermines the fundamental rationale underlying the patent system: to encourage innovation. The real world consequences of the court of appeals' conceptual error are enormous. The decision of the court of appeals unjustifiably forecloses holders of improvement patents from relying on the important evidentiary tool of commercial suc-

cess in defending their patents from claims of invalidity. The Court should grant the writ in this case to ensure that innovators are not discouraged by the legal system from investing in valuable improvements on their existing products.

CONCLUSION

For the reasons stated, review of the third question presented in the petition should be granted.

Respectfully submitted,

Roderick R. McKelvie
Counsel of Record
David H. Remes
Christian J. Pistilli*
Covington & Burling
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 662-5195

**Admitted in New York only; supervised by principals of the firm*

September 22, 2005

FILED
SEP 22 2005
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 05-236

IN THE

Supreme Court of the United States

MERCK & CO., INC.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONER

WILLIAM G. MCELWAIN
EDWARD C. DUMONT
WILMER CUTLER PICKERING
HALE AND DORR LLP
2445 M Street, N.W.
Washington, DC 20037

WILLIAM F. LEE
Counsel of Record
JOHN M. GOLDEN
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTEREST OF AMICUS CURIAE 1

STATEMENT 2

SUMMARY OF ARGUMENT 5

REASONS FOR GRANTING THE WRIT 6

I. THE FEDERAL CIRCUIT HAS DEPARTED FROM THIS COURT'S TEACHINGS AND PREVIOUSLY SETTLED LAW BY CONFLATING "COMMERCIAL SUCCESS" AND "FAILURE OF OTHERS" AS INDICATORS OF NONOBVIOUSNESS 6

II. PRECLUDING CONSIDERATION OF COMMERCIAL SUCCESS BECAUSE OF PRIOR EXCLUSIVE RIGHTS IMPROPERLY TRUNCATES THE OBVIOUSNESS INQUIRY AND REDUCES INCENTIVES FOR INNOVATION 11

III. THE DECISION BELOW WILL AFFECT A WIDE RANGE OF CASES AND TRANSFORM COMMERCIAL SUCCESS INTO AN ISSUE REQUIRING A COMPLEX THRESHOLD INQUIRY 14

CONCLUSION 18

TABLE OF AUTHORITIES

CASES

Page(s)

Amgen, Inc. v. *Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202 (D. Mass. 2004) 12
Anderson's-Black Rock, Inc. v. *Pavement Salvage Co.*, 396 U.S. 57 (1969) 7
Arkie Lures, Inc. v. *Gene Larew Tackle, Inc.*, 119 F.3d 953 (Fed. Cir. 1997) 9, 16
Black & Decker Manufacturing Co. v. *Sears, Roebuck & Co.*, 679 F.2d 1101 (4th Cir. 1982) 8
Bonita Boats, Inc. v. *Thunder Craft Boats*, 489 U.S. 141 (1989) 13
Brown & Williamson Tobacco Corp. v. *Philip Morris Inc.*, 229 F.3d 1120 (Fed. Cir. 2000) 7, 8
Cochrane v. *Deener*, 94 U.S. 780 (1876) 12
Consolidated Safety-Valve Co. v. *Crosby Steam Gage & Value Co.*, 113 U.S. 157 (1885) 8
Demaco Corp. v. *F. von Langsdorff Licensing Ltd.*, 851 F.2d 1387 (Fed. Cir. 1988) 16
Ecolochem, Inc. v. *Southern California Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000) 7, 9
Gillette Co. v. *S.C. Johnson & Son, Inc.*, 919 F.2d 720 (Fed. Cir. 1990) 10
Goodyear Tire & Rubber Co. v. *Ray-O-Vac Co.*, 321 U.S. 275 (1944) 8
Graham v. *John Deere Co.*, 383 U.S. 1 (1966) ..... *passim*
Greening Nursery Co. v. *J&R Tool Manufacturing Co.*, 376 F.2d 738 (8th Cir. 1967) 10
Hobbs v. *Beach*, 180 U.S. 383, 393 (1901) 8
Hotchkiss v. *Greenwood*, 42 U.S. (11 How.) 248 (1851) 7
Illinois Tool Works, Inc. v. *Sweetheart Plastics, Inc.*, 436 F.2d 1180 (7th Cir. 1971) 8, 9
In re Papesch, 315 F.2d 381 (C.C.P.A. 1963) 10
In re Soni, 54 F.3d 746 (Fed. Cir. 1995) 10

TABLE OF AUTHORITIES—Continued

Page(s)

Keystone Manufacturing Co. v. *Adams*, 151 U.S. 139 (1894) 8
Lorenz v. *F.W. Woolworth Co.*, 305 F.2d 102 (2d Cir. 1962) 15
Magowan v. *N.Y. Belting & Packing Co.*, 141 U.S. 332 (1891) 8
Merck KGaA v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) 12
Minerals Separation, Ltd. v. *Hyde*, 242 U.S. 261 (1916) 8
Ortho-McNeil Pharmaceutical, Inc. v. *Mylan Laboratories, Inc.*, 348 F. Supp. 2d 713 (N.D. W. Va. 2004) 10
Panduit Corp. v. *Denniston Manufacturing. Co.*, 810 F.2d 1561 (Fed. Cir. 1987) 13
Prima Tek II, L.L.C. v. *A-Roo Co.*, 222 F.3d 1372 (Fed. Cir. 2000) 12
Reiner v. *I. Leon Co.*, 285 F.2d 501 (2d Cir. 1960) 5, 8, 17
Safety Car Heating & Lighting Co. v. *General Electric Co.*, 155 F.2d 937 (2d Cir. 1946) 11
Sakraida v. *Ag Pro, Inc.*, 425 U.S. 273 (1976) 7
Sarkisian v. *Winn-Proof Corp.*, 697 F.2d 1313 (9th Cir. 1983) 8, 10
Smith v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1876) 8
Syntex (U.S.A.) LLC v. *Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005) 6, 14, 16
Topliff v. *Topliff*, 145 U.S. 156 (1892) 8
United States v. *Adams*, 383 U.S. 39 (1966) 7
Vulcan Engineering Co. v. *Fata Aluminum, Inc.*, 278 F.3d 1366 (Fed. Cir. 2002) 9
Washburn & Moen Manufacturing Co. v. *Beat 'Em All Barbed-Wire Co.*, 143 U.S. 275 (1892) 8
Winner International Royalty Corp. v. *Wang*, 202 F.3d 1340 (Fed. Cir. 2000) 16

TABLE OF AUTHORITIES—Continued

Page(s)

CONSTITUTIONAL AND STATUTORY PROVISIONS

U.S. Const. art. I, § 8, cl. 8 ..... 6, 13
35 U.S.C. § 103 ..... 3, 6
35 U.S.C. § 271 ..... 3, 12

MISCELLANEOUS

Boyer, Spencer H., *Commercial Success as Evidence of Patentability*, 37 Fordham L. Rev. 573 (1969) 9
Dreyfuss, Rochelle Cooper, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. Rev. 1 (1989) 9
Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), *available at* http://www.ftc.gov/os/003/10/innovationrpt.pdf 15
Food and Drug Administration, *NDAs Approved in Calendar Years 1990-2003 by Therapeutic Potentials and Chemical Types* (Mar. 2, 2005), *available at* http://www.fda.gov/cder/rdmt/pstable.htm 14
Grabowski, Henry G., *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science and Cents: Exploring the Economics of Biotechnology* 87 (John V. Duca & Mine K. Yücel eds., 2003), *available at* http://www.dallasfed.org/research/pubs/science/index.html. 2, 16
PhRMA, *Pharmaceutical Industry Profile 2004—Focus on Innovation* 2
PhRMA, *Pharmaceutical Industry Profile 2005—From Laboratory to Patient: Pathways to Biopharmaceutical Innovation*, *available at* http://www.phrma.org/publications/publications//2005-03-17.1143.pdf 1, 13

TABLE OF AUTHORITIES—Continued

Page(s)

Robbins, Richard L., Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169 (1964) 10, 17

U.S. Patent No. 6,476,006 (issued Nov. 5, 2002) 12

Wertheimer, Albert, et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, in 14 *Investing in Health: The Social and Economic Benefits of Health Care Innovation* (Irina Farquhar et al. eds., 2001) 14, 15

IN THE

Supreme Court of the United States

No. 05-236

MERCK & CO., INC.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONER

INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the nation's leading pharmaceutical research and biotechnology companies.[1] In 2004, PhRMA's members "invested an estimated $38.8 billion" in the discovery and development of new medicines. PhRMA,

[1] Letters from counsel for both parties consenting to the filing of this brief have been submitted to the Clerk. No counsel for a party authored any part of this brief, and no person or entity other than members of or counsel for PhRMA made a monetary contribution to the preparation or submission of this brief. Although petitioner Merck & Co., Inc. is one of PhRMA's more than thirty members (the names of all of which are available at http://www.phrma.org/whoweare/members/), petitioner did not contribute to the funding or drafting of this brief.

Pharmaceutical Industry Profile 2005—From Laboratory to Patient: Pathways to Biopharmaceutical Innovation 2, *available at* http://www.phrma.org/publications/publications//2005-03-17.1143.pdf. The societal benefits from such investment are undeniable. "New medicines generated 40 percent of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000." PhRMA, *Pharmaceutical Industry Profile 2004—Focus on Innovation*, at VII. "Since 1990, pharmaceutical research company scientists have invented and developed more than 300 completely new medicines, vaccines, and biologics approved by the Food and Drug Administration . . . ." *Id.* at 10.

PhRMA's members appreciate the importance of innovation—whether fundamental or incremental—to technological progress and social well-being. They also have an intimate appreciation of the importance of patent rights. In an industry where research and development is expensive and competition is fierce, strong patent protection is necessary for PhRMA's members to be able to recoup the costs of their investments. *See* Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science and Cents: Exploring the Economics of Biotechnology* 87, 88-92, 99-101 (John V. Duca & Mine K. Yücel eds., 2003), *available at* http://www.dallasfed.org/research/pubs/science/index.html. The Federal Circuit's decision in this case significantly undermines confidence in the ability of innovators to obtain and enforce patents on improvements and thereby substantially threatens the pace of continued innovation in the pharmaceutical industry.

STATEMENT

Petitioner Merck owns both the patent in suit (the '329 patent) and an earlier patent (the '077 patent). Pet. App. 2a, 24a, 44a-45a. The '077 patent claims a method of preventing or treating osteoporosis through the oral administration of alendronate. Merck secured approval from the Food and Drug Administration to market an alendronate preparation called Fosamax® for use in 5 or 10 milligram daily doses.

While effective, this daily regimen in practice led to gastrointestinal side effects in some patients. The '329 patent claims an improved method consisting of using 35 or 70 milligram doses of alendronate once a week. *Id.* at 3a-4a. The patent disclosure explains that, counter-intuitively, the increased dosage at more widely-spaced intervals leads to a pronounced reduction in the incidence of related gastrointestinal distress.

The dosing improvement was a commercial as well as a medical success. Pet. App. 22a-23a, 91a-93a. The '329 patent issued in 1999, and Merck obtained approval of 35 and 70 milligram doses in 2000. *Id.* at 44a, 92a. Commercial release of the corresponding new products was followed by both a sharp increase in the rate of sales growth for Fosamax® and a 10% jump in petitioner's share of the primary market for osteoporosis-treating drugs. *Id.* at 92a-93a.

In October 2000, respondent Teva sought FDA approval to market generic copies of Merck's weekly-dose Fosamax®. Pet. App. 4a, 44a. Merck filed suit under 35 U.S.C. § 271(e)(2)(A), arguing that sale of Teva's copies would infringe the '329 patent.[2]

Teva stipulated that sale of its proposed weekly-dose products would infringe the '329 patent, but Teva challenged the patent's validity and enforceability. Pet. App. 46a. Among other things, Teva argued that Merck's improvement claims were invalid because the claimed weekly-dosing regimen "would have been obvious at the time the invention was made to a person having ordinary skill in the art," 35 U.S.C. § 103(a). Teva relied in particular on two alleged prior-art references in an equipment manufacturer's newsletter, the *Lunar News*. These references suggested the possibility of using once-weekly doses (although in amounts different from the 35 and 70 milligram amounts recited in the '329 patent).

---

[2] In a separate suit, Teva's application for approval of a generic drug for daily use was found to infringe the '077 patent. Pet. App. 5a n.3.

After trial, the district court rejected Teva's obviousness argument. Pet. App. 73a-94a. In analyzing "secondary considerations" favoring a finding of nonobviousness, the district court concluded that Merck had shown both commercial success and a nexus between that success and the patented improvement. Pet. App. 91a, 93a. The court accordingly weighed commercial success along with other factors in concluding that Teva had not borne the burden of "prov[ing] by clear and convincing evidence that the '329 patent was obvious in light of prior art." *Id.* at 93a-94a.

The Federal Circuit reversed, holding the relevant claims "invalid as obvious." Pet. App. 25a. The court did not question the district court's factual findings that once-weekly Fosamax® was commercially successful and that there was a causal "nexus" between that success and the improvement claimed by the patent. *Compare id.* at 22a-24a *with id.* at 91a-93a. It held instead that the improvement's commercial success was not probative in this case. *Id.* at 23a-24a. To justify that holding, the court first tied the relevance of an invention's commercial success to the distinct question whether previous attempts to solve a problem "have been made and have failed." *Id.* at 23a (internal quotation marks omitted). It then reasoned that commercial success said nothing significant about whether Merck's invention was "non-obvious in relation to the ideas set forth in the *Lunar News* articles" because, in the court's view, Merck's earlier '077 patent and additional exclusive rights under the Federal Food, Drug, and Cosmetic Act meant that "others were legally barred from commercially testing the *Lunar News* ideas." *Id.* at 24a.

Merck petitioned for a panel rehearing and a rehearing en banc. In an opinion dissenting from the denial of rehearing en banc, Chief Judge Michel and Judges Lourie and Newman agreed that the panel's decision "erred in linking commercial success to the failure of others" and in "conclud[ing] that commercial success is not probative because 'others were legally barred' from commercially testing certain ideas." Pet. App. 38a. In their view, "the full court

should have reheard the appeal to eliminate the confusion in the law that the panel opinion creates." *Id.* at 39a.

SUMMARY OF ARGUMENT

An invention is not patentable if, at the time it was made, the claimed innovation would have been "obvious" to one of ordinary skill in the relevant art. It has long been settled law that evidence of an invention's commercial success is an independent "secondary consideration" tending to show that the invention was not obvious. *See, e.g., Graham* v. *John Deere Co.*, 383 U.S. 1, 17-18 (1966). The Federal Circuit has now held to the contrary. According to the Federal Circuit's new rule, commercial success supports nonobviousness only by acting as evidence of *another* factor: "failure of others" to have produced the same invention. Pet. App. 23a-24a.

That holding departs from precedent, experience, and reason. For well over a century, courts have recognized that commercial success can evidence patentable innovation in ways quite distinct from "failure of others." Commercial success can, for example, show a neutral (and sometimes, as here, expert) marketplace's enthusiastic appreciation of an invention's distinctive qualities. It can also confirm that the invention responded to a long-felt need. Like the other "secondary considerations" this Court has identified, commercial success can, by itself, be an important "sign post[]" in a court's assessment of otherwise "misty" questions of patentability. *Reiner* v. *I. Leon Co.*, 285 F.2d 501, 503-504 (2d Cir. 1960) (L. Hand, J.), *cited in Graham*, 383 U.S. at 35-36. The Court should therefore reject a rule tying the probative value of commercial success to an inference of failure of others.

The Court should also review and reject the Federal Circuit's new rule that an invention's commercial success cannot help show nonobviousness if the invention is an improvement of an earlier invention for which the patent holder had pre-existing exclusive rights in the United States. Exclusive rights under U.S. patent or food and drug

laws do not—and, with respect to activity abroad, cannot—prevent third parties from competing in a "race to improve." The Federal Circuit's rule improperly favors third-party improvers over original innovators who initially disclose their inventions at an early stage (as patent law encourages) and then proceed to improve them. The Federal Circuit's rule thereby weakens the incentives to create and disclose both the initial invention and follow-on improvements, contrary to patent law's purpose of "promot[ing] . . . Progress." U.S. Const. art. I, § 8, cl. 8.

The Federal Circuit's holdings threaten harm extending far beyond the confines of this case. Three judges below rightly identified the need to address "the confusion in the law" that the court's opinion has created. Pet. App. 39a. A later case has already directed that the holdings below should govern commercial-success analysis whenever the "active ingredient" in a drug "was previously patented." *Syntex (U.S.A.) LLC* v. *Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005). Further, those holdings are not limited to pharmaceutical inventions, but will apply equally in all fields of technology, significantly complicating the law in ways that run counter to the reasons identified by this Court for referring to considerations such as commercial success. This Court should grant review and confirm that the commercial success of an improvement invention is an independent consideration in favor of nonobviousness, without regard to a patent holder's pre-existing rights.

REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT HAS DEPARTED FROM THIS COURT'S TEACHINGS AND PREVIOUSLY SETTLED LAW BY CONFLATING "COMMERCIAL SUCCESS" AND "FAILURE OF OTHERS" AS INDICATORS OF NONOBVIOUSNESS

A claimed invention is not patentable if it "would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103. In the leading case on nonobviousness, *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966), this Court specifically listed an invention's "commercial success" and the "failure of others" to